DOCKET NO.: 03-04US

**Application No.:** 10/805,788

Office Action Dated: March 28, 2008

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:** 

1-2. (Cancelled).

3. (Withdrawn) A method for intranasal administration of calcitonin which comprises

administering intranasally to an individual a solution of calcitonin consisting essentially of

calcitonin, chlorobutanol at a concentration of 0.25% weight/weight, and water and having a

pH of about 3.5, sodium chloride at a concentration of about 0.85%, and optionally

hydrochloric acid in an amount sufficient to adjust the pH of the solution to about 3.5, and

wherein the aqueous solution has an oxygen at a content of less than about 5%.

4. (Withdrawn) The method of claim 3 wherein the calcitonin is present in solution at a

concentration of about 0.0355 weight/weight.

5. (Withdrawn) The method of claim 3 wherein the calcitonin formulation is

administered into a nose of an individual through an actuator tip as a spray, wherein the spray

has a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height

of 3.0 cm from the actuator tip.

6. (Withdrawn) The method of claim 5 wherein the spray produces droplets, wherein

less that 5% of the droplets are less than 10 microns in size.

7. (Withdrawn) The method of claim 5 wherein the spray has a spray pattern major axis

of about 31.2 mm and a minor axis of about 27.4 mm.

8. (Currently Amended) A composition consisting of comprising:

an aqueous solution of calcitonin at a concentration of about 0.0355% weight/weight;

chlorobutanol at a concentration of between about 0.25% and about 0.4% weight/weight;

sodium chloride at a concentration of about 0.85% weight/weight; and

a pH between about 3 to 4 hydrochloric acid in an amount sufficient to adjust the pH of the

solution to about 3.5; and

less than about 5% oxygen;

wherein the composition is suitable for intranasal administration in humans.

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## 9-11. (Cancelled)

12. (Currently Amended) A composition consisting of comprising:

an aqueous solution of calcitonin salmon at a concentration of 2200 International Units (I.U.) per ml;

chlorobutanol at a concentration of <u>between</u> about 0.25% <u>and about 0.4%</u> weight/weight; sodium chloride at a concentration of <u>about 0.85%</u> weight/weight; <u>and</u>

a pH between about 3 to 4 hydrochloric acid in an amount sufficient to adjust the pH of the solution to about 3.5; and

## less than about 5% oxygen;

wherein the composition is suitable for intranasal administration in humans.

13-15. (Cancelled)

16. (Currently Amended) A pharmaceutical composition <u>consisting of comprising</u>: an aqueous solution of calcitonin salmon at a concentration of 2200 International Units (I.U.) per ml;

chlorobutanol at a concentration of <u>between</u> about 0.25% <u>and about 0.4%</u> weight/weight; sodium chloride at a concentration of <u>about 0.85%</u> weight/weight; <del>and</del>

a pH between about 3 to 4 hydrochloric acid in an amount sufficient to adjust the pH of the solution to about 3.5; and

## less than about 5% oxygen;

wherein the composition is suitable for intranasal administration in humans.

17-19. (Cancelled)

20. (Previously Presented) A pharmaceutical device comprising a composition according to claim 8 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.

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21. (Previously Presented) A pharmaceutical device comprising a composition according to claim 8 and an actuator to produce an aerosol spray of the composition, wherein the spray has a spray pattern major axis of about 31.2 mm and a minor axis of about 27.4 mm.

- 22. (Previously Presented) A pharmaceutical device comprising a composition according to claim 8 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, wherein less than 5% of the droplets are smaller than 10 microns in size.
- 23. (Previously Presented) A pharmaceutical device comprising a composition according to claim 12 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
- 24. (Previously Presented) A pharmaceutical device comprising a composition according to claim 12 and an actuator to produce an aerosol spray of the composition, wherein the spray has a spray pattern major axis of about 31.2 mm and a minor axis of about 27.4 mm.
- 25. (Previously Presented) A pharmaceutical device comprising a composition according to claim 12 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, wherein less than 5% of the droplets are smaller than 10 microns in size.
- 26. (Previously Presented) A pharmaceutical device comprising a composition according to claim 16 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip.
- 27. (Previously Presented) A pharmaceutical device comprising a composition according to claim 16 and an actuator to produce an aerosol spray of the composition, wherein the spray has a spray pattern major axis of about 31.2 mm and a minor axis of about 27.4 mm.

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28. (Previously Presented) A pharmaceutical device comprising a composition according to claim 16 and an actuator to produce an aerosol spray of the composition, the spray having a spray pattern ellipticity ratio of from about 1.0 to about 1.4 when measured at a height of 3.0 cm from the actuator tip, wherein less than 5% of the droplets are smaller than 10 microns in size.